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PATENT
ATTY. DOCKET NO. L-F/180DV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Goethel et al.
Serial No. : 09/764,630
Filed : January 18, 2001
For : Improved Syringe/Plunger Coupling

Art Unit: 3763
Examiner: M. Hayes

Assistant Commissioner of Patents
BOX: RESPONSE FEE
Washington, DC 20231

TRANSMITTAL OF APPEAL BRIEF

1. Transmitted herewith, in triplicate, is the APPEAL BRIEF in this application, with respect to the Notice of Appeal filed on December 2, 2002.

2. STATUS OF APPLICANT

This application is on behalf of:

- ☒ Other than a Small Entity
☐ Small Entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted.
☐ Enclosed is a verified statement to establish Small Entity status

3. FEE FOR FILING APPEAL BRIEF

Pursuant to 37 CFR 1.17(f), the fee for filing the Appeal Brief is:

- ☐ Small Entity (\$160.00)
☒ Large Entity (\$320.00)

Appeal Brief Fee Due \$ \$320.00

4. EXTENSION OF TERM

The proceedings herein are for a patent application and the provisions of 37 CFR 1.136 apply. Complete (a) or (b) as applicable.

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid in an envelope addressed to: Assistant Commissioner of Patents, Box: Response FEE, Washington, D.C. 20231 on: February 3, 2003

Ginger M. Graff

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(a)____ Applicant petitions for an extension of time under 37 CFR 1.136 for the total number of months checked below:

Extension (months)	Fee for other than <u>small entity</u>	Fee for <u>small entity</u>
_____ one month	\$ 110.00	\$ 55.00
_____ two months	\$ 410.00	\$205.00
_____ three months	\$ 930.00	\$465.00
_____ four months	\$1,450.00	\$725.00
_____ five months	\$1,970.00	\$985.00

Extension fee due with this request \$_____.

If an additional extension of time is required, please consider this a petition therefor.
(Check and complete the next item, if applicable)

_____ An extension for _____ months has already been secured and the fee paid thereof of \$_____ is deducted from the total fee due for the total months of extension now requested. Extension fee due with this request \$_____.

OR

(b) X Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition for extension of time.

5. TOTAL FEE DUE

The total Fee due is:

Appeal Brief Fee of \$ 320.00

Extension Fee (if any) \$_____.

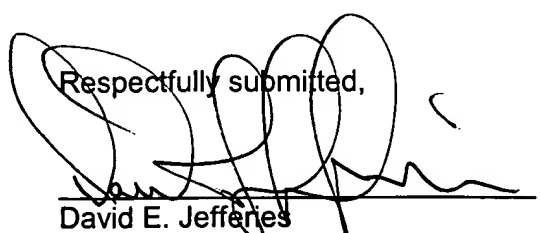
TOTAL FEE DUE \$ 320.00

6. FEE PAYMENT AND FEE DEFICIENCY

X Attached is a check in the sum of \$ 320.00

X If any additional fee for claims or extension of time is required, charge Account No. 23-3000.

Respectfully submitted,


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Ginger M. Graff 02/03/03
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Serial No. 09/764,630
Filed: January 18, 2001
Applicant: James H. Goethel, Robert G. Bergen
Title: **SYRINGE/PLUNGER COUPLING**
Art Unit: 3763
Examiner: M. Hayes
Atty Docket: L-F-180DV

Cincinnati, Ohio 45202

February 3, 2003

APPEAL BRIEF

Real Party in Interest

The subject application is owned by Liebel-Flarsheim Company, a corporation of Delaware, and having a place of business at 2111 East Galbraith Road, Cincinnati, Ohio 45237.

Related Appeals and Interferences

There are no other appeals or interferences known to appellant, the appellant's legal representative, or assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

On December 2, 2002, appellant appealed from the final rejection of claims 1-11 under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,300,031 (the "Neer et al. '031 patent").

Status of Amendments

An amendment responsive to the final rejection was filed with the U.S. Patent & Trademark Office on even date with the filing of this Appeal Brief. This amendment was filed to (1) address a typographical error in claim 2, and (2) respond to the Examiner's disapproval of the proposed drawing corrections. A copy of this amendment is attached as Exhibit A.

Summary of the Invention

The invention of the present application is directed to a coupling mechanism between a plunger of a syringe and a plunger drive ram of an injector that receives the syringe. This coupling mechanism results in movement of the syringe plunger that is directly cooperative with movement of the plunger drive ram. This allows for enhanced accuracy in the volume and timing of fluid injected into a subject over syringes and injectors of the prior art.

Prior art coupling mechanisms include "jaw and button" coupling mechanisms, such as that disclosed in the Neer et al. '031 patent. In such a coupling mechanism, the "button" is mushroom-shaped, including an extension protruding from the rearward face of the syringe plunger, and topped by a cap. This button contacts "jaws" located on the forward end of the plunger drive ram of an injector. These jaws

snap around the button of the syringe plunger, thereby connecting the syringe plunger to the plunger drive ram. However, this coupling mechanism does not result in a perfect fit between the jaws on the plunger drive ram and the button on the rearward face of the syringe plunger. Rather, it results in a degree of "backlash" between the mating sections of the coupling mechanism. This "backlash" occurs because, due to the spacing between the jaws and button, the syringe plunger does not move cooperatively with the plunger drive ram upon motorized, automated movement of the plunger drive ram. Rather, an injector exhibiting this coupling mechanism features an initial movement of the plunger drive ram and a subsequent responsive movement of the syringe plunger. Thus, there is a lag time in deploying the syringe plunger to inject fluids into a subject. This is a problem because many medical applications require an extremely high degree of accuracy, especially in the timing and volume of substances injected into the body. The lag time exhibited by this coupling mechanism of the prior art creates a reduced degree of accuracy.

The present invention eliminates lag time and "backlash" and allows for increased accuracy in the injection of fluids into a subject. In particular, the increased accuracy of the present invention results from the "backlash-free" grip of the coupling mechanism recited in the claims of the present application. The coupling mechanism of the present invention involves a coupling element on the plunger drive ram, such as a cam cleat, which grips directly onto an extension on the rearward face of the syringe plunger. The direct and tight grip created by the interaction of the drive ram coupling element and the extension on the syringe plunger eliminates the lag time between movement of the plunger drive ram and the syringe plunger. In fact, the very structure

of the extension of the syringe plunger facilitates this direct and "backlash-free" grip. In particular, and as recited in the claims, the rearward facing extension on the syringe plunger exhibits no discontinuity in its transverse cross-sections along the portion of the extension adapted to be gripped by the coupling mechanism. Thus, any coupling between the extension and the plunger drive ram must be direct, which results in cooperative movement of the syringe plunger and drive ram, as opposed to responsive movement.

Issues

Whether claims 1-11 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,300,031 (the "Neer et al. '031 patent").

Grouping of Claims

Claims 1-11 stand or fall together.

The Examiner's Rationale

The Examiner's rationale for rejecting claims 1-11 as anticipated by the Neer et al. '031 patent in the final rejection is as follows: The Examiner states that the Neer et al. '031 patent anticipates claims 1-11 in that that patent "shows a syringe having a barrel, [a] plunger with a knurled coupling element, [a] conical front, syringe mating sections comprising an annular flange fixed to the syringe body, and an anterior cavity in the coupling element". (Office Action, August 1, 2002, p.2). The Examiner also states that the Neer et al. '031 patent shows a "movable face plate movable by a rotatable lever". (Id.). This was the same rejection issued in the first Office Action, dated January 29, 2002, and to which Applicants had responded by arguing that the

coupling element of the Neer et al. '031 patent exhibited discontinuities in its transverse cross-sections and thus failed to anticipate claims 1-11.

In responding to the arguments that Applicants made in response to the January 29, 2002 Office Action, the Examiner stated that the rejection of that Office Action would be maintained because (1) the coupling element of the device of the Neer et al. '031 patent exhibits "no discontinuities in cross-sections taken along the transverse axis", and (2) the extension disclosed in the Neer et al. '031 patent exhibits "no discontinuities in cross-sections taken along the longitudinal axis over a portion of the extension adapted to be gripped by a coupling element". (Id., at p. 3).

Argument

I. Claim Rejections 35 U.S.C. § 102:

As noted above, the Examiner has rejected claims 1-11 of the present application under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,300,031, issued to Neer et al. By rejection under 35 U.S.C. § 102(b), the Examiner therefore suggests that the Neer et al. reference discloses each and every limitation of claims 1-11 of the present application. Applicants respectfully disagree.

A. Claim Recitations at Issue

Independent claims 1 and 8 of the present application recite a rearwardly facing coupling element (extension) on a syringe's plunger, wherein the coupling element "exhibits no discontinuity in its transverse cross-sections along the portion of said extension gripped by a coupling mechanism".

The primary issue to be raised by Applicants on this Appeal is whether the rearwardly facing extension of the coupling element disclosed in the Neer et al. '031 patent "exhibits no discontinuity in its transverse cross-sections along the portion of said extension adapted to be gripped by a coupling mechanism" as is recited by claims 1 and 8 of the present application.

B. Discussion

As stated above, the Examiner has maintained the rejections cited in the Office Action dated January 29, 2002 because he believes that (1) the device of the Neer et al. '031 patent "has no discontinuities in cross-sections taken along the transverse axis", and (2) the device of the Neer et al. '031 patent "has no discontinuities in cross-sections taken along the longitudinal axis over a portion of the extension adapted to be gripped by a coupling element". (Office Action, August 1, 2002, p.3). Applicants disagree.

1. The Two (2) Cross-Sections Identified By The Examiner

In reviewing the August 1, 2002 Office Action, it appears the Examiner reads the claims to potentially recite two separate cross-sections, each of these cross-sections being defined differently. In particular, the Examiner suggests that there are (1) cross-sections which are taken through a longitudinal axis of the coupling element (i.e., longitudinal cross-sections), and (2) cross-sections taken transverse to the longitudinal axis of the coupling element. (Id.). The Examiner's belief with respect to the cross-sections recited in the present claims is incorrect in that the claims refer to

cross-sections that are "transverse" (i.e. perpendicular to the longitudinal axis of the coupling element). This is the only cross-section referenced in the application.

2. The Only Cross-Sections Disclosed By The Present Application Are Those Taken Transverse To The Longitudinal Axis Of The Coupling Element

Applicants assert that any cross-sections described in the application and in the response to the January 29, 2002 Office Action are cross-sections taken transverse to the longitudinal axis of the coupling element. As an initial matter, nowhere do the Applicants discuss or describe a "longitudinal cross-section" as is suggested by the Examiner at page 3 of the August 1, 2002 Office Action ["Applicant argues that Neer has discontinuities in cross-sections taken along the longitudinal axis (i.e., longitudinal cross-sections)..."]. Applicants assume that the Examiner may have mistakenly believed that the Applicants suggested a "longitudinal cross-section" in Applicants' response to the first Office Action (response dated April 29, 2002) at page 8 ("Applicants further note that such a coupling element would exhibit discontinuity in cross-sections taken along its longitudinal axis..."). However, Applicants were attempting only to note that the claim recites the absence of discontinuities in the transverse cross-sections (i.e., cross-sections of the coupling element taken in a plane perpendicular to the longitudinal axis of the coupling element). The full response quotation reads as follows:

"Applicants further note that such a coupling element would exhibit discontinuity in cross-sections taken along its longitudinal axis, in that a cross-section taken at the cap of the button would be of a much greater diameter than a cross-section taken along the extension protruding from the rearward face of the syringe plunger." (Response, April 29, 2002, p.8).

Applicants were referring to transverse cross-sections, because only transverse cross-sections would be circular at both the cap and the extension of the button with the cap being of greater diameter.

Applicants have stated in the claims of their application that their coupling mechanism exhibits no discontinuities in its transverse cross-sections. (See claims 1 and 8). "Transverse direction" is defined in the application, with respect to the face plate, as "perpendicular to the longitudinal axis of the syringe plunger extension and the drive ram ". (See p.15, lines 19-20). Applicants therefore submit that "cross-sections taken along the longitudinal axis" are not the subject of the claims of the present application. Applicants further submit that, as a result, the only cross-sections relevant to an analysis of the claims of the present application are those taken transverse to the longitudinal axis of the coupling element.

3. The Neer et al. '031 Patent Does Not Anticipate Claims 1-11 Of The Present Application Because The Coupling Element Disclosed By Neer Does Exhibit Discontinuity In Cross-Sections Taken Along The Transverse Axis.

As stated above, one reason the Examiner states that he has maintained the rejections is because he states that the coupling element of the Neer et al. '031 patent exhibits "no discontinuities in cross-sections taken along the transverse axis". This is incorrect. With reference to the Figures and the disclosure of the Neer et al. '031 patent, Applicants note that the coupling element of the Neer et al. reference includes a T- or mushroom-shaped button located at the end of the plunger drive ram (See reference number 96 in Fig. 4). As can be seen, this button includes an extension

protruding from the rearward face of the syringe plunger, topped by a cap. Applicants further note that such a coupling element would exhibit discontinuity in cross-sections taken transverse to its longitudinal axis, in that adjacent transverse cross-sections taken at the junction of the extension and cap would have a substantial discontinuous change in area. By contrast, independent claims 1 and 8 of the present application, which are the only independent claims of the present application, explicitly state that the rearwardly facing extension of the coupling mechanism exhibits "no discontinuity of its transverse cross-sections along a portion of said extension adapted to be gripped by a coupling mechanism". Applicants further note that the entire mushroom-shaped coupling element and particularly the junction of the extension and cap, is gripped in the Neer et al. '301 patent. Thus, the coupling element of Neer exhibits discontinuities along that portion of the extension "adapted to be gripped" by a coupling mechanism.

C. Conclusion

Thus, Applicants submit that the Neer et al. '031 patent fails to disclose each and every claimed element of the present application in claims 1 and 8. Applicants thus submit that claims 1 and 8 are not anticipated by the Neer et al. reference. Since claims 1 and 8 are not anticipated, Applicants further submit that dependent claims 2-7 and 9-11 are also not anticipated by the Neer et al. '031 patent. Applicants therefore respectfully request a reversal of the Examiner's rejection.

Summary

For the foregoing reasons, appellant believes that the Examiner's rejection of claims 1-11 was erroneous, and reversal of his decision is respectfully requested.

Respectfully submitted,

Wood, Herron & Evans, L.L.P.

By: 

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Appendix

1. A syringe for mounting to an injector for injecting fluids into an animal subject, said syringe comprising:
 - a cylindrical barrel;
 - a plunger snugly slidable in said cylindrical barrel, said plunger having a rearwardly facing drive ram engaging coupling element thereon in the shape of a rearwardly facing extension exhibiting no discontinuity in its transverse cross-sections along a portion of said extension adapted to be gripped by a coupling mechanism; and
 - a discharge tip in fluid communication with a forward end of said cylindrical barrel.
2. The syringe of claim 12 wherein said rearwardly facing coupling element is knurled.
3. The syringe of claim 1 further comprising a conical front wall disposed between said cylindrical barrel and said discharge tip.
4. The syringe of claim 1 further comprising syringe mating sections positioned in a plane perpendicular to the longitudinal axis of the cylindrical barrel, wherein said syringe mating sections facilitate mounting of said syringe to an injector.
5. The syringe of claim 4 wherein said syringe mating sections are arranged so as to align with mating sections disposed on said injector.

6. The syringe of claim 5 wherein said syringe mating sections include a radially outwardly extending annular flange.

7. The syringe of claim 1 wherein said rearwardly facing coupling element includes an interior cavity.

8. An injector for injecting fluids from a syringe into an animal subject, comprising;

a housing;

a plunger drive ram bidirectionally movable along an axis and mounted within
5 said housing;

a motor drivingly coupled to said drive ram to selectively advance and retract said drive ram along said axis into and out of said housing;

a syringe for mounting to said injector comprising a cylindrical barrel, a plunger snugly slidable in said cylindrical barrel, said plunger having a rearwardly facing drive
10 ram engaging coupling element thereon in the shape of a rearwardly facing extension exhibiting no discontinuity of its transverse cross-sections along a portion of said extension adapted to be gripped by a coupling mechanism, and a discharge tip in fluid communication with said cylindrical barrel; and

a movable face plate used to position a syringe relative to said injector housing
15 to permit said drive ram to engage and move said plunger within said syringe.

9. The injector of claim 8 further comprising injector mating sections, said syringe further comprising syringe mating sections positioned in a plane perpendicular to the axis of the body of the syringe and arranged so as to align with the injector mating sections.

10. The injector of claim 8, wherein said face plate further comprises a rotatable lever used for translatory motion of said face plate, said lever movable between locked and unlocked positions, wherein motion of said lever to said locked position causes attachment of a syringe to said injector housing by translating said rearward facing coupling element of said syringe plunger against a coupling mechanism of said plunger drive ram to facilitate cooperative movement of said syringe plunger and said plunger drive ram to inject fluids into said animal subject.

11. The injector of claim 10 wherein movement of said rotatable lever from said locked to said unlocked position results in translatory movement of said face plate along a plane perpendicular to the axis of said plunger drive ram to disengage said rearward facing coupling element of said syringe plunger from a coupling mechanism of said plunger drive ram.